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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:

J. Ronald Wilk

Serial No.: 09/800,360

Filed: March 6, 2001

Title: WOUND TREATMENT SOLUTION
AND METHOD FOR USING SAME

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Attorney Docket No. P-121944.00002.001

Group Art Unit: 1616

Examiner: Barbara P. Badio

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Rule 1.132 Declaration of J. Ronald Wilk

1. My name is J. Ronald Wilk. I am over the age of eighteen (18) years, and I have never been convicted of a felony.
2. I have personal knowledge of the facts stated herein, and they are true and correct.
3. I am the inventor of the patent application entitled "Wound Treatment Solution and Method of Using Same," Serial No. 09/800,360. As such, I am familiar with the invention, as well as the development, usages and properties of the invention described therein.

PROFESSIONAL BACKGROUND

4. I have worked in the field of medicine for over 37 years. I graduated from the Chicago College of Osteopathy in 1964. While in private practice as a doctor of Osteopathy, I served as an active staff member of the Columbia Medical Center of Plano, Texas. Also, I served as medical director of Garland General Hospital in Garland, Texas, and as medical director of the Southwest U.S. Government Defense Contracting Administrative Services in Dallas, Texas.

5. In addition to my primary professional focus on the practice of medicine, I have pursued many special interest areas including lifestyle management, preventative medicine, hypertension, lipid disorder, migraine headaches, fibromyalgia, Epstein Barr virus and others. These pursuits have involved extensive research and frequent speaking engagements to professional and educational organizations.

COMPARISON OF THE PRESENT INVENTION WITH CITED REFERENCES

6. The invention described by Warren mentions the use of an optional antimicrobial agent for its personal care composition. The patent provides a long list of substances that exhibit some antimicrobial properties suitable for addition to the overall composition. In particular, Warren mentions cedar leaf and tea tree oils as possible antimicrobial agents.

7. Our use of cedar leaf oil and, more particularly, *thuja occidentalis*, is not merely to utilize its properties as an antibiotic. Specifically, testing has shown that the use of "thuja oil," in combination with the other claimed components of the present invention, produces an overall synergistic effect to provide a host of unexpected benefits.

8. In short, the overall combination of the claimed invention simultaneously promotes healing, reduces swelling, reduces pain, removes redness and encourages fluid removal. As one of skill in the art, I am unaware of a topical composition that provides all of these beneficial properties.

9. Attached please find evidence supporting the overall synergistic properties of the present invention, labeled as Exhibits A, B and C.

10. Exhibit A illustrates 34-day testing of the present invention upon the leg ulcers of the patient. Exhibits B and C illustrate 34-day testing of the present invention upon the patient's feet. These pictures illustrate the dramatic improvement experienced by the patient over a 34-day period. This patient had been suffering with multiple ulcers over a 5-month period. Over that time, the patient utilized various prior art topical compositions in an effort to overcome this painful condition, with little improvement. Upon review of the attached Exhibits, it is apparent that the present invention caused dramatic improvements to the patient's condition. Specifically, it can be seen that significant healing occurred during the 34-day period as well as reduced redness and reduced fluid accumulation.

11. Based upon test results, it is my opinion as one skilled in the art that the use of *thuja* oil in combination with the other claimed elements of the present invention produces a significant synergistic effect not exhibited by prior art topical compositions.

12. The medical field has long desired a topical composition capable of promoting healing and acting as a dehydrating (anti-inflammatory agent), an analgesic (reduces pain), and an althema (reduces redness). To the best of my knowledge, there is no topical composition, other than the present invention, exhibiting each of these synergistic properties while, at the same time, healing an area in a dramatically reduced time frame. The present invention satisfies a long felt need that has existed in the medical field for many years.

13. The Examiner states that tea tree oil and cedar tree oil are equivalent. I respectfully disagree with the Examiner on this point. The addition of tea tree oil, also known as *melaleuca alternifolia*, to the other elements of the claimed invention does not produce the same synergistic effect produced by the use of *thuja* oil. In short, it is my opinion as one of skill in the art that tea tree oil and *thuja* oil are not interchangeable, nor are they equivalent.

14. On another matter, a host of medications utilize zinc oxide. However, anhydrous lanoline is rarely used as an ointment base for this type of topical solution. In fact, the use of anhydrous lanolin provides the overall composition of the present invention with an antibacterial lubricating agent. Thus, the use of anhydrous lanolin in combination with the other claimed elements provides the patient with a cool, soothing feeling along with the above-described synergistic effects. This feature of the present invention is not described in the patents cited by the Examiner.

15. As the person signing below, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements

and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issues thereon.


J. RONALD WILK

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